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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,372	04/09/2001	Morten Peter Meldal	11225.13US01	9680

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/17/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,372

Applicant(s)

MELDAL ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-19 and 48-57 is/are pending in the application.
- 4a) Of the above claim(s) 15,16,18, 49, 51-52 and 54-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14,17,19,48,50 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 9, & 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 2/24/03 in Paper No. 12 is acknowledged and entered. Claims 2-9, and 20-47 are canceled by the amendment. Claims 1, and 10-19 are amended by the amendment. Claims 48-57 are added by the amendment.

Further, applicant has indicated that claim 1 be cancelled *after* entry of the amendment. Thus claim 1 is cancelled *after* entry of the amendment.

2. Claims 10-19, and 48-57 are pending.

Election/Restrictions

3. Applicant's election with traverse of Group II (Claims 10-19, and *new claims 48-57*) in Paper No. 8 is acknowledged. The traversal is moot since applicant has cancelled the nonelected inventions (e.g. Claims 1-9, and 20-47) in Paper No. 12. Additionally, the issue of the linking claims 28-29, and 33 is considered moot since these claims are cancelled.

4. Applicant's species election with traverse in Paper No. 8 and 12 is acknowledged. Applicant has elected the following species for the elected invention (Claims 1-45 and 73):

- a. A species of building block unit (protecting group): *N*-sec-butyl-glycine monomer.
- b. A species of building block linker (functional group): amide bond.
- c. A species of template molecule: solid substrate.
 - i. A species of solid substrate: polystyrene.

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- ii. A species of functional group: amide functional group.

5. Claims 15-16, 18, 49, 51-52, and 54-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a *nonelected species*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement is still deemed proper and is therefore made **FINAL**.

6. Claims 10-14, 17, 19, 48, 50, and 53 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “protecting group” in claims 10-13 is used by the claim to mean “monomer and/or linker for the monomer”, while the accepted meaning is “group that protect the terminal functional group during synthesis.” The term is indefinite because the specification does not clearly redefine the term. Additionally, from the specification (see page 5, lines 28-29 to page 6, lines 1-2) it appears

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that the term "target group" is synonymous to the term "protecting group". The examiner has interpreted the term "protecting group" as the accepted meaning.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 10-12, 17, 19, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundberg et al. (US Patent 5,624,711).

Sundberg et al. disclose a method for the synthesis of peptides, oligonucleotides, or other small molecules (target compounds) on a solid support (template; refers to claim 17) (col. 1, lines 64-67). The solid support comprise of polymers with amide functional groups (col. 14, lines 49-53). These functional groups are synthesis initiation sites, which are protected by protecting groups (col. 12, lines 33-46; col. 4, lines 6-23). Thus the method of Sundberg et al. anticipates the presently claimed method.

11. Claims 10-12, 14, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomalia et al. (US Patent 5,714,166).

Tomalia et al. disclose a cascade reaction method for the unimolecular assemblage of dendrimer (target compound) (col. 3, lines 4-65; col. 11, lines 36-67). The method comprises a) an initiator core (template); b) an interior layers composed of repeating unit (target group); c) an

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exterior surface of terminal functionality (functional group) (col. 11, lines 45-50; col. 12, lines 32-55; col. 12, lines 56-67 to col. 13, lines 1-4); d) protecting groups to protect the terminal functionality and control the assemblage of the repeating unit (col. 13, lines 17-35; col. 25, lines 34-38; col. 26, lines 23-30). The protecting groups are removed by a chemical reaction. The functional group comprise of amino group (col. 13, lines 17-35) (refers to claim 14). Thus the method of Tomalia et al. anticipates the presently claimed method.

12. Claims 10-12, 14, and 53 rejected under 35 U.S.C. 102(b) as being anticipated by Newkome et al. (US Patent 5,886,126).

Newkome et al. disclose a method of a cascade polymeric synthesis wherein the method steps includes the dendrimerizing a mixture of branched monomers on a substrate (template) wherein the monomers (target group) have heterogeneously functionalized branches and homogenous connectivity to the substrate (col. 2, lines 60-65). The dendrimerizing step comprise of reacting the monomer mixture with the substrate surface, which is comprised of protected functionalities (col. 4, lines 62-67 to col.5, lines 1-18). The functional group of the substrate comprises of amino group (col. 3, lines 17-29). The complimentary protected groups form a linkage between the substrate surface and the monomers (col. 4, line 67 to col. 5, lines 1-7) and the non-complimentary protected groups are removed by a chemical reaction (col. 5, lines 30-40). Thus the method of Newkome et al. anticipates the presently claimed method.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 10-12, 14, 17, 19, 48, 50, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomalia et al. (US Patent 5,714,166) and Shchepinov et al. (US Patent 6,455,071 B1: *filing 08/27/1997*).

Tomalia et al. disclose a cascade reaction method for the unimolecular assemblage of dendrimer (target compound) (col. 3, lines 4-65; col. 11, lines 36-67). The method comprises a) an initiator core (template); b) an interior layers composed of repeating unit (target group); c) an exterior surface of terminal functionality (functional group) (col. 11, lines 45-50; col. 12, lines 32-55; col. 12, lines 56-67 to col. 13, lines 1-4); d) protecting groups to protect the terminal functionality and control the assemblage of the repeating unit (col. 13, lines 17-35; col. 25, lines

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34-38; col. 26, lines 23-30). The protecting groups are removed by a chemical reaction. The functional group comprise of amino group (col. 13, lines 17-35) (refers to claim 14).

The method of Tomalia et al. does not expressly disclose that the template comprise of a solid support.

Shchepinov et al. disclose a method of assembling branched structures from building block and a plurality of blocked functional groups at the outer ends of the structure (col. 1, lines 54-64). The core molecule comprise of at least two sites wherein chemical growth is initiated and attachment to a solid support (col. 2, lines 44-56). The material of the solid support includes plastic (col. 4, lines 15-17).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the template as a solid support as taught by Shchepinov et al. in the method of Tomalia et al. One of ordinary skill in the art would have been motivated to include the template as a solid support in the method of Tomalia et al. for the advantage of providing a segregated surface into which defined areas to direct the chemical reaction (col. 3, lines 62-65) since both Tomalia et al. and Shchepinov et al. disclose the method of dendrimeric synthesis (Tomalia: col. 11, lines 36-67; Shchepinov: col. 1, lines 10-40). One of ordinary skill in the art would have reasonably expectation of success in the combination of Tomalia et al. and Shchepinov et al. because Shchepinov et al. disclose examples of synthesis of dendrimeric structures from solid support (col. 12 to col. 14; figures 4-6).

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16. Claims 10-12, 14, 17, 19, 48, 50, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newkome et al. (US Patent 5,886,126) and Shchepinov et al. (US Patent 6,455,071 B1: *filing 08/27/1997*).

Newkome et al. disclose a method of a cascade polymeric synthesis wherein the method steps includes the dendrimerizing a mixture of branched monomers on a substrate (template) wherein the monomers (target group) have heterogeneously functionalized branches and homogenous connectivity to the substrate (col. 2, lines 60-65). The dendrimerizing step comprise of reacting the monomer mixture with the substrate surface, which is comprised of protected functionalities (col. 4, lines 62-67 to col.5, lines 1-18). The functional group of the substrate comprises of amino group (col. 3, lines 17-29). The complimentary protected groups form a linkage between the substrate surface and the monomers (col. 4, line 67 to col. 5, lines 1-7) and the non-complimentary protected groups are removed by a chemical reaction (col. 5, lines 30-40). Thus the method of Newkome et al. anticipates the presently claimed method.

The method of Newkome et al. does not expressly disclose that the template comprise of a solid support.

Shchepinov et al. disclose a method of assembling branched structures from building block and a plurality of blocked functional groups at the outer ends of the structure (col. 1, lines 54-64). The core molecule comprise of at least two sites wherein chemical growth is initiated and attachment to a solid support (col. 2, lines 44-56). The material of the solid support includes plastic (col. 4, lines 15-17).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the template as a solid support as taught by Shchepinov et al. in

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the method of Newkome et al. One of ordinary skill in the art would have been motivated to include the template as a solid support in the method of Newkome et al. for the advantage of providing a segregated surface into which defined areas to direct the chemical reaction (col. 3, lines 62-65) since both Newkome et al. and Shchepinov et al. disclose the method of dendrimeric synthesis (Newkome: col. 1, lines 11-17; Shchepinov: col. 1, lines 10-40). One of ordinary skill in the art would have reasonably expectation of success in the combination of Newkome et al. and Shchepinov et al. because Shchepinov et al. disclose examples of synthesis of dendrimeric structures from solid support (col. 12 to col. 14; figures 4-6).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

mct
November 17, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER